

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2014-H-1043)

Complainant

v.

Veedersburg Star Market Inc.
d/b/a Veedersburg Food Basket,

Respondent.

Docket No. C-14-1537

Decision No. CR3385

Date: September 24, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Veedersburg Star Market Inc. d/b/a Veedersburg Food Basket, at 300 North Main Street, Veedersburg, Indiana 47987, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Veedersburg Food Basket impermissibly sold smokeless tobacco to a minor and failed to verify, by means of photo identification containing a date of birth, that the purchaser was 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Veedersburg Food Basket previously admitted to three violations of regulations found at 21 C.F.R. pt. 1140 and, therefore, CTP seeks to impose a \$5,000 civil money penalty against Respondent Veedersburg Food Basket.

As provided for in 21 C.F.R. §§ 17.5 and 17.7, on July 24, 2014, CTP served the complaint on Respondent Veedersburg Food Basket by United Parcel Service. In the

complaint and accompanying cover letter, CTP explained that, within 30 days, Respondent should pay the penalty, file an answer, or request an extension of time in which to file an answer. CTP warned Respondent that, if it failed to take one of these actions within 30 days, the Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering it to pay the full amount of the proposed penalty.

Respondent Veedersburg Food Basket has neither filed an answer within the time prescribed, nor requested an extension of time within which to file an answer. Pursuant to 21 C.F.R. § 17.11, I assume that the facts alleged in the complaint (but not its conclusory statements) are true. Specifically:

- CTP previously issued a warning letter to Respondent Veedersburg Food Basket on December 20, 2012, citing a violation of 21 C.F.R. pt. 1140 on November 2, 2012, at Respondent's business establishment, 300 North Main Street, Veedersburg, Indiana 47987;
- On September 16, 2013, CTP initiated a previous civil money penalty action, CRD Docket Number C-13-1311, FDA Docket Number FDA-2013-H-1114, against Respondent for three violations of 21 C.F.R. pt. 1140 within a twenty-four month period. CTP alleged those violations to have occurred on November 2, 2012, and March 4, 2013;
- The previous action concluded when Steve Simko, Respondent's authorized representative, settled the claims on Respondent's behalf. On September 18, 2013, Mr. Simko signed an Acknowledgment Form in which he "admitt[ed] that the violations . . . occurred, waiv[ed] his ability to contest the violations in the future, and stat[ed] that he understood that that violations may be counted in determining the total number of violations for purposes of future enforcement actions." The Administrative Law Judge closed the case on October 17, 2013;
- At approximately 8:08 p.m. on January 30, 2014, at Respondent's business establishment, 300 North Main Street, Veedersburg, Indiana 47987, FDA-commissioned inspectors documented Respondent's staff selling a package of Grizzly Long Cut Premium Wintergreen smokeless tobacco to a person younger than 18 years of age. The inspectors also documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older.

These facts establish Respondent Veedersburg Food Basket's liability under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if sold or distributed in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387f(d); *see* 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b).

The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; *see* 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). Under 21 C.F.R. § 1140.14(a), no retailer may sell smokeless tobacco to any person younger than 18 years of age. Under 21 C.F.R. § 1140.14(b)(1), retailers must verify, by means of photographic identification containing a purchaser's date of birth, that no smokeless tobacco purchasers are younger than 18 years of age.

Under 21 C.F.R. § 17.2, a \$5,000 civil money penalty is permissible for five violations of the regulations found at 21 C.F.R. pt. 1140 within a thirty-six month period.

Order

For these reasons, I enter default judgment in the amount of \$5,000 against Respondent Veedersburg Star Market Inc. d/b/a Veedersburg Food Basket. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

_____/s/
Catherine Ravinski
Administrative Law Judge